IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

| | | |
|---|---|---|
| Gena Norris, et al. | § | |
| | § | |
| Plaintiff, | § | |
| | § | Civil Action No. 4:18−cv−02762 |
| v. | § | |
| | § | |
| McKesson Corporation, et al., | § | |
| | § | |
| Defendants. | § | |

**AMENDED ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT**

Defendant Bracco Diagnostics Inc. ("BDI") answers and responds to Plaintiffs' Complaint as follows:

**PRELIMINARY STATEMENT**

Many of the paragraphs of the Complaint and of the individual allegations contained therein are addressed jointly to all remaining Defendants without distinction between them. BDI is not a corporate affiliate of those Defendants, has no knowledge – actual, constructive, or otherwise – as to actions, conduct, business practices, or behavior of those Defendants and they are entities over which BDI has no control. Accordingly, in the responses that follow, BDI responds solely on its own behalf, and denies knowledge or information as to the truth or falsity of any and all allegations as to the other remaining Defendants, unless expressly averred otherwise.

## ANSWER TO SECTION ENTITLED "BACKGROUND AND INVOLVED PARTIES"

1. BDI admits that Chuck Norris is an actor. BDI is without sufficient information to form a belief as to the truth of allegations in Paragraph 1 of the Complaint regarding Gena Norris's employment, and therefore must deny the same. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint regarding Plaintiffs' interests, hobbies, or family, and therefore must deny the same. BDI denies the remaining allegations in Paragraph 1 of the Complaint, and specifically denies that retention of gadolinium, if any, causes adverse health effects in patients with normal renal function.

2. BDI denies the allegations in Paragraph 2 of the Complaint.

3. BDI denies the allegations in Paragraph 3 of the Complaint.

4. BDI admits that MultiHance® and ProHance® are FDA-approved contrast agents dispensed by prescription and that the FDA has approved their product labeling and package inserts. BDI further states that, on December 19, 2017, the FDA again reiterated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks." BDI denies the remaining allegations in Paragraph 4 of the Complaint.

5. BDI denies the allegations in Paragraph 5 of the Complaint.

6. BDI denies the allegations in Paragraph 6 of the Complaint.

7. BDI denies the allegations in Paragraph 7 of the Complaint.

## ANSWER TO SECTION ENTITLED "MANUFACTURING DEFENDANTS"

8. BDI admits that BDI markets and sells ProHance® and MultiHance®, FDA-approved contrast agents dispensed by prescription. BDI denies that ProHance® or

MultiHance® were administered to Plaintiff Gena Norris. BDI states that all named defendants other than BDI listed in Paragraph 8 of the Complaint have been dismissed. BDI denies the remaining allegations in Paragraph 8 of the Complaint.

9. BDI admits that it is a Delaware corporation with its principal place of business in New Jersey, and further admits that it is registered to conduct business in Texas and California. BDI admits that it markets and sells ProHance® and MultiHance®, FDA-approved contrast agents dispensed by prescription, in the United States, and that ProHance® and MultiHance® are approved by the FDA for such marketing and sale. BDI denies the remaining allegations in Paragraph 9 of the Complaint.

10. No answer is required to Paragraph 10 of the Complaint, as this party has been dismissed from the action.

11. No answer is required to Paragraph 11 of the Complaint, as this party has been dismissed from the action.

12. No answer is required to Paragraph 12 of the Complaint, as this party has been dismissed from the action.

13. No answer is required to Paragraph 13 of the Complaint, as this party has been dismissed from the action.

14. No answer is required to Paragraph 14 of the Complaint, as this party has been dismissed from the action.

15. No answer is required to Paragraph 15 of the Complaint, as this party has been dismissed from the action.

16. No answer is required to Paragraph 16 of the Complaint, as this party has been dismissed from the action.

17. BDI admits that it markets and sells ProHance® and MultiHance®, FDA-approved contrast agents dispensed by prescription, in the United States, and that ProHance® and MultiHance® are approved by the FDA for such marketing and sale. BDI denies the remaining allegations in Paragraph 17 of the Complaint.

18. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint, and therefore must deny the same.

19. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 19 of the Complaint, and therefore must deny the same.

20. The allegations in Paragraph 20 of the Complaint are not allegations of fact and require no response from BDI.

21. The allegations in Paragraph 21 of the Complaint are not allegations of fact and require no response from BDI.

**ANSWER TO SECTION ENTITLED "DISTRIBUTOR DEFENDANTS"**

22. BDI admits that McKesson Corporation distributes ProHance® and MultiHance®. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Corporation with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Corporation, in that Plaintiffs have failed to sufficiently plead that McKesson Corporation distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas. BDI denies the remaining allegations in Paragraph 22 of the Complaint.

23. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 23 of the Complaint regarding McKesson Corporation's state of incorporation, and principal place of business, and therefore denies the

same. BDI further denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Corporation with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Corporation, in that Plaintiffs have failed to sufficiently plead that McKesson Corporation distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas.

24. BDI admits, upon information and belief, the allegations in Paragraph 24 of the Complaint.

25. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Corporation with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Corporation, in that Plaintiffs have failed to sufficiently plead that McKesson Corporation distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas.

26. BDI admits, upon information and belief, that McKesson Medical-Surgical, Inc. distributes ProHance® and MultiHance®. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Medical-Surgical, Inc. with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Medical-Surgical, Inc., in that Plaintiffs have failed to sufficiently plead that McKesson Medical-Surgical, Inc. distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas. BDI denies the remaining allegations in Paragraph 26 of the Complaint.

27. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 27 of the Complaint regarding McKesson

Medical-Surgical, Inc.'s state of incorporation and principal place of business, and authorization to conduct business in California, and therefore denies the same. BDI further denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Medical-Surgical, Inc. with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Medical-Surgical, Inc., in that Plaintiffs have failed to sufficiently plead that McKesson Medical-Surgical, Inc. distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas.

28. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint, and therefore denies the same.

29. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Medical-Surgical, Inc. with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Medical-Surgical, Inc., in that Plaintiffs have failed to sufficiently plead that McKesson Medical-Surgical, Inc. distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas.

30. No answer is required to Paragraph 30 of the Complaint, as this party has been dismissed from the action.

31. No answer is required to Paragraph 31 of the Complaint, as this party has been dismissed from the action.

32. No answer is required to Paragraph 32 of the Complaint, as this party has been dismissed from the action.

33. No answer is required to Paragraph 33 of the Complaint, as this party has been dismissed from the action.

34. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint, and therefore must deny the same.

35. BDI is without sufficient information to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint, and therefore must deny the same.

36. The allegations in Paragraph 36 of the Complaint are not allegations of fact and require no response from BDI.

37. The allegations in Paragraph 37 of the Complaint are not allegations of fact and require no response from BDI.

38. The allegations in Paragraph 38 of the Complaint are not allegations of fact and require no response from BDI.

**ANSWER TO SECTION ENTITLED "JURISDICTION AND VENUE"**

39. BDI admits that subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332 and venue is proper pursuant to 28 U.S.C. § 1391. BDI denies the remaining allegations in Paragraph 39 of the Complaint.

40. To the extent that Paragraph 41 of the Complaint states legal conclusions, no response is required. BDI denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of BDI with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over BDI, in that Plaintiffs have failed to sufficiently plead that Plaintiff Gena Norris was administered ProHance® or MultiHance® within the State of Texas. BDI further denies that Plaintiffs have sufficiently pleaded the requisite minimum contacts of McKesson Corporation and McKesson Medical-Surgical, Inc. with the State of Texas that would support this Court's or any other Texas court's exercise of personal jurisdiction over McKesson Corporation or McKesson Medical-Surgical, Inc., in that Plaintiff has failed to sufficiently plead that McKesson Corporation or McKesson Medical-Surgical, Inc.

distributed the ProHance® or MultiHance® that was allegedly administered to Plaintiff Gena Norris and that such administration occurred within the State of Texas.

41. BDI denies the allegations in Paragraph 41 of the Complaint.

42. BDI denies the allegations in Paragraph 42 of the Complaint.

43. BDI denies the allegations in Paragraph 43 of the Complaint.

44. BDI denies the allegations in Paragraph 44 of the Complaint.

45. BDI denies the allegations in Paragraph 45 of the Complaint.

**ANSWER TO SECTION ENTITLED "FACTS"**

46. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 46 of the Complaint regarding Plaintiff Gena Norris's alleged medical history, and therefore denies the same. BDI further states that, on December 19, 2017, the FDA again reiterated that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks." To the extent that Paragraph 46 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies such allegations. BDI denies the remaining allegations contained in Paragraph 46 of the Complaint.

47. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 47 of the Complaint regarding Plaintiff Gena Norris's alleged medical history, and therefore denies the same. BDI denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 47 of the Complaint.

48. BDI denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI further states that Paragraph 48 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 48. BDI denies the remaining allegations contained in Paragraph 48 of the Complaint.

49. BDI denies the allegations contained in Paragraph 49 of the Complaint.

50. BDI admits that gadolinium is a heavy metal, rare earth element that may or may not be toxic depending on the circumstances. BDI denies the remaining allegations contained in Paragraph 50 of the Complaint.

51. BDI admits that gadolinium is a heavy metal, rare earth element that may or may not be toxic depending on the circumstances. BDI denies the remaining allegations contained in Paragraph 51 of the Complaint.

52. BDI admits that it markets and sells ProHance® and MultiHance®, FDA-approved contrast agents dispensed by prescription. BDI denies that either was administered to Plaintiff Gena Norris and denies the remaining allegations in Paragraph 52 of the Complaint.

53. BDI denies the allegations in Paragraph 53 of the Complaint.

54. BDI denies the allegations in Paragraph 54 of the Complaint.

55. BDI denies the allegations in Paragraph 55 of the Complaint.

56. In response to Paragraph 56 of the Complaint, BDI admits that ProHance® and MultiHance® are FDA-approved contrast agents dispensed by prescription and accompanied by FDA-approved labeling and package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the ProHance® and MultiHance® labeling and package inserts were approved by the FDA and

transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 56 of the Complaint.

57. BDI denies the allegations contained in Paragraph 57 of the Complaint.

58. BDI denies the allegations contained in Paragraph 58 of the Complaint.

59. BDI denies the allegations contained in Paragraph 59 of the Complaint.

60. BDI denies the allegations contained in Paragraph 60 of the Complaint.

61. BDI denies the allegations contained in Paragraph 61 of the Complaint.

62. BDI denies the allegations contained in Paragraph 62 of the Complaint.

**ANSWER TO SECTION ENTITLED**
**"APPLICATION OF THE DISCOVERY RULE"**

63. BDI denies the allegations in Paragraph 63 of the Complaint.

64. BDI denies the allegations in Paragraph 64 of the Complaint.

65. BDI states that the allegations contained in Paragraph 65 of the Complaint are vague and ambiguous, such that BDI is unable to formulate a response, in that it is not clear what is meant by "the inventors of linear gadolinium-based contrast agents," and therefore denies the allegations contained in Paragraph 65. To the extent that Paragraph 65 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

66. Paragraph 66 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 66 of the Complaint.

67. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 67 of the Complaint regarding Magnevist, and therefore denies the same. To the extent that Paragraph 67 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies such allegations.

68. Paragraph 68 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 68. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

69. Paragraph 69 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 69. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

70. Paragraph 70 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 70. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

71. Paragraph 71 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 71. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

72. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 72 of the Complaint regarding Omniscan, and therefore denies the same. To the extent that Paragraph 72 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

73. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 73 of the Complaint regarding Magnevist, and therefore denies the same. To the extent that Paragraph 73 of the Complaint calls for medical or scientific conclusions prior to discovery, any such response by BDI would be premature at this time, and BDI therefore denies such allegations. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

74. BDI denies the allegations in Paragraph 74 of the Complaint.

75. BDI states that the allegations contained in Paragraph 75 of the Complaint do not constitute "a short and plain statement" of Plaintiff's alleged claim, such that BDI is unable to formulate a response. BDI admits that ProHance® and MultiHance® are FDA-approved contrast agents dispensed by prescription and accompanied by FDA-approved labeling and

package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the ProHance® and MultiHance® labeling and package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 75 of the Complaint.

76. Paragraph 76 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 76. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

77. BDI states that the allegations contained in Paragraph 77 of the Complaint do not constitute "a short and plain statement" of Plaintiff's alleged claim, such that BDI is unable to formulate a response. BDI admits that ProHance® and MultiHance® are FDA-approved contrast agents dispensed by prescription and accompanied by FDA-approved labeling and package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the ProHance® and MultiHance® labeling and package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on

December 19, 2017. BDI denies the remaining allegations contained in Paragraph 77 of the Complaint.

78. BDI is without sufficient information to form a belief as to the truth, meaning or intent of the allegations contained in Paragraph 78 of the Complaint, and therefore denies the same. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

79. Paragraph 79 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 79. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

80. Paragraph 80 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 80. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

81. Paragraph 81 of the Complaint calls for medical or scientific conclusions prior to discovery, such that any response by BDI would be premature at this time, and BDI therefore denies the allegations contained in Paragraph 81. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

82. In response to Paragraph 82 of the Complaint, BDI states that the FDA's public statement speaks for itself. BDI further admits that MultiHance® is an FDA-approved contrast

agent dispensed by prescription and accompanied by FDA-approved labeling and package inserts. BDI further admits that any and all contraindications, warnings, precautions, adverse reactions, and/or other information in the MultiHance® labeling and package inserts were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. BDI fulfilled its obligation under the law to provide adequate warnings and instructions. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017. BDI denies the remaining allegations contained in Paragraph 82 of the Complaint.

83. BDI denies the allegations in Paragraph 83 of the Complaint.

84. BDI denies the allegations in Paragraph 84 of the Complaint.

85. BDI denies the allegations in Paragraph 85 of the Complaint.

86. BDI denies the allegations in Paragraph 86 of the Complaint.

**ANSWER TO SECTION ENTITLED**
**"FIRST CAUSE OF ACTION STRICT PRODUCT LIABILITY: FAILURE TO WARN"**

87. In response to Paragraph 87 of the Complaint, BDI adopts, realleges and incorporates herein by reference its answers, affirmative defenses and other matters constituting an avoidance as set forth in paragraphs 1-86 of this Answer and in its Affirmative and Other Defenses.

88. BDI denies the allegations contained in Paragraph 88 of the Complaint.

89. BDI denies the allegations contained in Paragraph 89 of the Complaint.

90. BDI denies the allegations contained in Paragraph 90 of the Complaint.

WHEREFORE, BDI prays that Plaintiffs take nothing by way of the First Cause of Action in their Complaint, for judgment in BDI's favor as to Plaintiffs' First Cause of Action, for BDI's costs and fees incurred herein, and for such further relief deemed just and proper.

**ANSWER TO SECTION ENTITLED**
**"SECOND CAUSE OF ACTION NEGLIGENCE"**

91. In response to Paragraph 91 of the Complaint, BDI adopts, realleges and incorporates herein by reference its answers, affirmative defenses and other matters constituting an avoidance as set forth in paragraphs 1-90 of this Answer and in its Affirmative and Other Defenses.

92. To the extent Paragraph 2 of the Complaint states legal conclusions, no response is required. To the extent BDI may be required to respond, BDI denies that it breached any duty, and denies the remaining allegations contained in Paragraph 92 of the Complaint.

93. BDI denies the allegations contained in Paragraph 93 of the Complaint.

94. BDI denies the allegations contained in Paragraph 94 of the Complaint.

95. BDI denies the allegations contained in Paragraph 95 of the Complaint.

96. BDI denies the allegations contained in Paragraph 96 of the Complaint. BDI further denies that gadolinium retention, if any, has been found to cause adverse health effects in patients with normal kidney function, as the FDA again reiterated on December 19, 2017.

97. BDI denies the allegations contained in Paragraph 97 of the Complaint.

WHEREFORE, BDI prays that Plaintiffs take nothing by way of the Second Cause of Action in his Complaint, for judgment in BDI's favor as to Plaintiffs' Second Cause of Action, for BDI's costs and fees incurred herein, and for such further relief deemed just and proper.

**DISMISSED CAUSES OF ACTION**

BDI states that Plaintiffs' Third, Fourth, and Fifth Causes of Action have been dismissed, and require no response from this defendant.

**ANSWER TO SECTION ENTITLED**
**"SIXTH CAUSE OF ACTION NEGLIGENCE"**

119. In response to Paragraph 119 of the Complaint, BDI adopts, realleges and incorporates herein by reference its answers, affirmative defenses and other matters constituting an avoidance as set forth in paragraphs 1-97 of this Answer and in its Affirmative and Other Defenses.

120. BDI admits, upon information and belief, the allegations in Paragraph 120 of the Complaint.

121. BDI denies the allegations in Paragraph 121 of the Complaint.

**ANSWER TO SECTION ENTITLED**
**"PRAYER FOR RELIEF"**

BDI denies that Plaintiffs are entitled to any relief as requested in their "Prayer for Relief."

**AFFIRMATIVE AND OTHER DEFENSES**

By alleging the matters set forth below, BDI does not admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters. If necessary and/or in the alternative, BDI raises the following defenses available in the State of Texas and any State or Commonwealth of the United States whose laws might be deemed controlling in this case, but reserves the right to amend its Answer to raise any additional defenses which it may have against Plaintiffs' claims:

1. Plaintiffs' claims and causes of action are barred by the applicable statute of limitations, and/or repose, and/or may be otherwise untimely.

2. Plaintiffs fail to state a claim upon which relief can be granted.

3. Plaintiffs fail to plead their claims against BDI with sufficient particularity.

4. ProHance® and MultiHance® are contrast imaging agents which are available only upon prescription of a licensed physician. Any warnings that BDI gave were transmitted to prescribing physicians and/or healthcare providers. Under applicable state law, BDI fulfilled its obligation to provide adequate warnings and instructions. Plaintiffs' claims are therefore barred pursuant to the learned intermediary doctrine.

5. Plaintiff failed to heed the warnings provided by BDI and/or the warnings provided by his physicians, and his failure to heed warnings directly and proximately caused any injuries or damages sustained by him or Plaintiff.

6. If Plaintiffs sustained the injuries or damages as alleged, said injuries and expenses were directly and proximately caused by the acts and omissions (wrongful or otherwise),negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more parties other than BDI over whom BDI had no supervision or control and for whose actions and omissions BDI has no legal responsibility. BDI is not liable for negligence and violated no duty that may have been owed to Plaintiffs.

7. BDI's activities conformed to all state and federal statutes, regulations, and industry standards based upon the state of the knowledge that existed at the time.

8. Plaintiffs' recovery is barred and/or should be reduced under the applicable law because of Plaintiffs' contributory negligence or fault, comparative negligence or fault, culpable conduct, intentional acts, assumption of risk, and/or want of care.

9. The incident and damages, if any, of which Plaintiff complains were proximately caused by the fault of third persons not parties to this suit. Inasmuch as the liability of BDI and the right of Plaintiff to recover in this litigation can only be determined after the percentages of fault of any parties of the incident are determined, including responsible third parties who are

currently unknown and unknowable to BDI, BDI seeks an adjudication of the percentage of fault of each and every person whose fault contributed to this incident.

10. Plaintiffs' injuries and damages, if any, resulted from an intervening or superseding cause or causes and any act or omission on the part of BDI was not the proximate and/or competent producing cause of such alleged injuries or damages.

11. Plaintiffs' Complaint fails to state a claim upon which relief can be granted in that the methods, standards and techniques utilized with respect to the design, manufacture, marketing, distribution, and sale of ProHance® and MultiHance®, including adequate warnings and instructions with respect to the products' use included in the products' package insert and other literature conformed to the applicable state of the art. The products in question, including their FDA-approved labeling, complied with the state of scientific and medical knowledge available to BDI at the time of its manufacture, distribution, and sale.

12. With respect to each and every purported cause of action, the acts of BDI were at all times done in good faith and without malice.

13. Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

14. Plaintiffs' claims are barred in whole or in part because BDI provided legally adequate "directions or warnings" as to the use of the product at issue within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

15. Plaintiffs' claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment f to Section 6, of the Restatement (Third) of Torts: Products Liability.

16. With respect to each and every cause of action, Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate Plaintiffs' claims to a negligence cause of action.

17. ProHance® and MultiHance® complied with all applicable state and federal statutes regarding the products in question, including product safety regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged in by the Complaint. The products at issue were reasonably fit, suitable, and safe for their respective intended uses, demonstrating that due care was exercised with respect to the design, manufacture, testing, marketing, distribution, and sale of ProHance® and MultiHance®. In the event that Plaintiffs' claims are not barred, BDI is entitled to a presumption that the products in question are free from any defect or defective condition as the plans or design for the products or the methods and techniques of manufacturing, inspecting, and testing the products were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the products or the methods and techniques of manufacturing, inspecting, and testing the products were adopted.

18. Plaintiffs' claims are barred because ProHance® and MultiHance® were neither defective nor unreasonably dangerous in their respective design, manufacture, distribution, or marketing, and were reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiffs' recovery.

19. If Plaintiffs sustained the injuries or damages as alleged, said injuries or damages were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of ProHance® or MultiHance®, thereby barring Plaintiffs' recovery against BDI.

20. Plaintiffs' claims are barred to the extent Plaintiffs knew the condition of ProHance® and MultiHance®, appreciated the risks of injury flowing from use of the products, and nevertheless proceeded to use the products without regard to the danger of such risks. As a

result, Plaintiffs gave informed consent and/or assumed the risk of injury of which they now complain.

21. The extent of any risk associated with the use of the products at issue, the existence of which is not admitted, was, at the time of the distribution of said products by BDI, unknown and could not have been known by the use of ordinary care.

22. The public interest in the benefit and availability of the products which are the subject matter of this action precludes liability, if any, resulting from any activities undertaken by BDI, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there exists a risk inherent in the subject products, then such risk, if any, is outweighed by the benefits of the products.

23. Plaintiffs' failure to warn claim is barred given that BDI had no duty to warn of risks of which it neither knew nor should have known at the time the products were designed, distributed, and manufactured.

24. Plaintiffs' injuries and damages, if any, were the result of an idiosyncratic reaction that BDI could not have reasonably foreseen, thereby barring Plaintiffs' recovery.

25. Plaintiffs' claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or contemporaneous) unrelated to any conduct of BDI or condition of the products ProHance® or MultiHance®, thereby barring Plaintiffs' recovery.

26. Plaintiffs have not sustained an ascertainable loss of property or money, nor any actual injury or damages.

27. Plaintiffs' claims are barred under the doctrine of economic loss.

28. Plaintiffs failed to mitigate their alleged damages.

29. BDI's advertisements and labeling with respect to the products which are the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Unites States Constitution and this State.

30. BDI is entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

31. BDI denies any liability, but if BDI is ultimately found liable to Plaintiffs, then it should only be liable for its equitable share of Plaintiffs' recovery since any liability which would be found against BDI will be insufficient to impose joint liability.

32. If Plaintiffs recover from BDI, BDI is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiffs' alleged damages.

33. If Plaintiff's Complaint is held to contain a claim upon which relief may be granted, then Plaintiff's recovery, if any, should be limited by § 33.001 of the Texas Civil Practice & Remedies Code. If in fact, Plaintiff's Complaint is held to contain a claim upon which relief may be granted, then Plaintiff's recovery, if any, not barred by § 33.001, should be reduced pursuant to § 33.012 of the Texas Civil Practice & Remedies Code.

34. BDI's liability, if any, should be limited and governed by § 33.013 and § 33.015 of the Texas Civil Practice & Remedies Code.

35. BDI asserts its right to a credit and to make an election of credit for purposes of a settlement entered into with one or more Defendants in this case pursuant to Texas Civil Practice & Remedies Code § 33.012.

36. BDI affirmatively pleads that, in the event exemplary damages are awarded, such damages may not exceed two times the amount of economic damages plus an amount equal to any non-economic damages not to exceed $750,000, or $200,000, whichever is greater, pursuant to Texas Civil Practice & Remedies Code § 41.008.

37. Plaintiff's claims against BDI are specifically barred by Texas Civil Practice & Remedies Code § 82.007. The warnings provided with BDI's products were those approved by the FDA for pharmaceutical products that were approved by the FDA. BDI is therefore entitled to a rebuttable presumption of no liability with respect to the allegations involving failure to provide adequate warnings or information.

38. BDI reserves the right to assert any and all defenses available under Section 402A of the Restatement (2nd) of Torts and/or Sections 1-20 of the Restatement (3rd) of Torts: Products Liability.

39. To the extent Plaintiff seeks to recover medical or healthcare expenses, BDI is entitled to a limitation based on the amount actually paid or incurred. Tex. Civ. Prac. & Rem. Code § 41.0105. In addition, upon information and belief, some or all of Plaintiff's damages will be replaced or indemnified, in whole or in part, from collateral sources, and BDI is, therefore, entitled to a collateral source offset.

40. Plaintiffs' damages, if any, are barred or reduced by the doctrine of avoidable consequences.

41. To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, BDI's liability, if any, should be precluded or reduced accordingly.

42. To the extent Plaintiffs seek recovery of punitive or exemplary damages against BDI, unless BDI's liability for punitive damages and the appropriate amount of punitive

damages is required to be established by clear and convincing evidence, any award of punitive damages would violate BDI's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the United States Constitution and any applicable state constitution, and would be improper under the common law, public policies, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

43. To the extent Plaintiffs seek recovery of punitive or exemplary damages against BDI, any such claim of Plaintiffs for punitive damages against BDI cannot be maintained because there was no act or omission by BDI that was oppressive, fraudulent, or malicious. Additionally, any award of punitive damages under the applicable law would be unlawful and unauthorized, and would be void for vagueness, both facially and as applied, as a result of, among other deficiencies, the absence of adequate notice of what conduct is subject to punishment; the absence of adequate notice of what punishment may be imposed; and the absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that a jury may impose, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitution, and the common law and public policies of that state.

44. To the extent Plaintiffs seek recovery of punitive damages against BDI, any such claim of Plaintiffs for punitive damages against BDI cannot be maintained because any award of punitive damages under the applicable law would be by a jury that (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from

awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including residence, wealth, and corporate status of BDI, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is permitted to award punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any, (7) is not subject to adequate, independent, de novo trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards and in conformity with the United States Constitution as amended or any applicable State constitution. Any such verdict would violate BDI's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process and equal protection provisions of any applicable state constitution, and would be improper under the common law and public policies of that state.

45. Additionally, punitive damages may not be recovered to the extent such damages are: (1) imposed where state law is impermissibly vague, imprecise, or inconsistent, (2) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, or (3) imposed on the basis of anything other than BDI's conduct within the State where Plaintiffs resides, or in any other way subjecting BDI to impermissible multiple punishment for the same alleged wrong.

46. To the extent Plaintiffs seek recovery of punitive or exemplary damages against BDI, any award of punitive damages based on anything other than BDI's conduct in connection

with the design, manufacture, and sale of ProHance® or MultiHance® would violate the due process clause of the Fourteenth Amendment of the United States Constitution and the due process provisions of the applicable state constitution, and would be improper under the common law and public policies of that state, because any other judgment for punitive damages in this case cannot protect BDI against impermissible punishment for the same wrong and against punishment for extraterritorial conduct, including conduct that is lawful in states other than the applicable state. In addition, any award would violate principles of comity under the laws of that state.

47. BDI incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny.

48. BDI assert the provisions of all applicable statutory caps on damages of any sort, including compensatory, punitive, non-economic or exemplary damages, under applicable regulations and/or laws.

49. There was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiffs or reduced the alleged risk, without substantially impairing the usefulness, safety, efficacy, or intended purpose of ProHance® or MultiHance®, thereby barring Plaintiffs' recovery.

50. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

51. The BDI products at issue have been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 301, *et seq.,* and regulations promulgated thereunder. Therefore, Plaintiffs' claims predicated on state tort law and alleging that ProHance® or MultiHance® are unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

52. To the extent that Plaintiffs assert claims based on BDI's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

53. Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating drugs, including the products at issue, and is specifically charged with determining the content of warnings and labeling for drugs.

54. Plaintiffs' claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

55. BDI is entitled to the protections and limitations afforded under the law of Plaintiffs' state of residence and any other state whose law is deemed to apply in this case.

56. The Complaint fails to give BDI reasonable notice of facts sufficient to complete a choice of law analysis. Pending a determination of applicable law, BDI has pleaded all applicable affirmative defenses under Texas law, and reserves the right to assert further or

additional affirmative defenses if it is determined that such defenses exist under applicable state law(s).

57. To the extent Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate BDI's rights under the United States Constitution.

58. Plaintiffs received all or substantially all of the benefit from the subject product that Plaintiffs hoped and intended to receive, and to that extent, any damages and/or restitution that Plaintiffs might be entitled to recover from BDI must be correspondingly barred or reduced.

59. Plaintiffs' claims are barred by laches, waiver, accord and satisfaction, payment, release, res judicata, estoppel, spoliation of evidence, and/or the applicability of arbitration and award.

60. This case may be subject to dismissal or stay on the grounds of *forum non conveniens*.

61. Plaintiffs are not entitled to recover attorneys' fees under any applicable law.

62. BDI adopts, by reference, each and every defense asserted by any other defendant in this matter that are applicable to BDI.

**PRAYER**

WHEREFORE, Defendant Bracco Diagnostics, Inc. prays that:

1. Plaintiffs take nothing by reason of their Complaint;
2. the Complaint against this defendant be dismissed in its entirety;
3. Defendant recover its costs; and
4. this Court award such other relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Defendant Bracco Diagnostics, Inc. demands trial by jury on all claims so triable.

Dated: October 10, 2018

Respectfully submitted,

**CLARK HILL STRASBURGER**

/s/ Michael A. Walsh

**Michael A. Walsh**
*Attorney-in-Charge*
Texas State Bar. No. 00790146
S.D. Texas Bar No. 21846
**Elizabeth B, Kamin**
Texas State Bar No. 02620900
S.D. Texas Bar No. 7417
**Elizabeth F. Griffin**
Texas State Bar No. 24092450
S.D. Texas Bar No. 3228156

909 Fannin Street, Suite 2300
Houston, Texas 77010
Tel: (214) 651-4459
Fax: (214) 659-4085
michael.walsh@clarkhillstrasburger.com
betsy.kamin@clarkhillstrasburger.com
elizabeth.griffin@clarkhillstrasburger.com

*Attorneys for Defendant*
*Bracco Diagnostics Inc*.

Of Counsel:

**BAKER STERCHI COWDEN & RICE, L.L.C.**

Thomas N. Sterchi
(admitted pro hac vice)
Paul S. Penticuff
(admitted pro hac vice)
2400 Pershing Road, Suite 500
Kansas City, MO 64108
Telephone: (816) 471-2121
Facsimile: (816) 472-0288

## CERTIFICATE OF SERVICE

This is to certify that on October 10, 2018, I electronically filed the foregoing document with the Clerk of the Court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the court. The electronic case filing system sent a "notice of Electronic Filing" to the attorneys of record who have consented in writing to accept this Notice as service of this document by electronic means, all others have been served via certified mail, return receipt requested.

/s/ Michael A. Walsh